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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,801	12/09/2000	David Kenneth Johnson	Johnson 60/17024	2575

7590 12/17/2004

DEANNA J. NELSON  
104 TASMAN COURT  
CARY, NC 27513

EXAMINER
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VENCI, DAVID J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/733,801	<b>Applicant(s)</b> JOHNSON, DAVID KENNETH	
	<b>Examiner</b> David J Venci	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 October 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-19 is/are rejected.
- 7) ☒ Claim(s) 9-19 is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Election/Restrictions***

Applicant's election with traverse of Invention V, claims 12-15, in the reply filed on October 22, 2004 is acknowledged. Notwithstanding Applicant's arguments presented in the reply, Inventions II-VII (claims 9-19) are rejoined.

Applicant argues that Invention I and Inventions II-VII should be rejoined because (1) Applicant does not disclose or teach that the composition of Invention I can be used in a manner asserted by Examiner (i.e. as a contrast agent) in the prior Office Action, and (2) lengthy and arduous experimentation is needed to show that the composition of Invention I is useful in a manner asserted by Examiner. Applicant's arguments have been carefully considered but are not persuasive. Both arguments (1) and (2) neither address nor negate the propriety of Examiner's restriction requirement set forth in the prior Office Action. As stated previously, the product of Invention I, as claimed, can be used in a materially different process of using that product (MPEP 806.05(h)).

Applicant argues that Invention I and Invention VIII should be rejoined because (1) Applicant does not disclose or teach that his chelate-fluorophore tracer composition can be used in a manner asserted by Examiner (i.e. as a chelation therapeutic), (2) Applicant does not disclose or teach that the composition of Invention I can be used in a manner asserted by Examiner (i.e. as a contrast agent), and (3) lengthy and arduous experimentation is needed to show that the composition of Invention I is useful in a manner asserted by Examiner (i.e. as a contrast agent). Applicant's arguments have been carefully considered but are not persuasive. With respect to (1), claims 20-21 recite a test kit comprising "a chelating agent" or "EDTA." Applicant's argumentation directed to the ability of his chelate-fluorophore tracer composition to function as a chelation therapeutic are not applicable here.

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Applicant argues that Invention II-VII and Invention VIII should be rejoined because (1) Applicant does not disclose or teach that the product of Invention VIII can be used in a manner asserted by Examiner (i.e. as a contrast agent) in the prior Office Action, and (2) lengthy and arduous experimentation is needed to show that the product of Invention VIII is useful in a manner asserted by Examiner. Applicant's arguments have been carefully considered but are not persuasive. Both arguments (1) and (2) neither address nor negate the propriety of Examiner's restriction requirement set forth in the prior Office Action. As stated previously, the product of Invention VIII can be used in a materially different process of using that product (MPEP 806.05(h)).

The restriction requirement is deemed proper and is made FINAL. Claims 1-8 and 20-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 3, the preamble recitation of "chelate-fluorophore tracer composition" is indefinite because it appears that a fluorophore is not a required claim limitation. For example, if both R1 and R2 are H, then the composition does not contain a fluorophore.

The recitation of "fused into a ring system" is indefinite because it is not clear whether R3 and R4 are fused into the same ring system or are each fused into a separate ring system.

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In claims 9-11, the recitation of "identical dilutions" is indefinite because it is not clear how dilutions are identical or what other dilutions are identical. In addition, The recitation of "less than that producing a baseline signal for the target tracer composition" is indefinite because it is not clear what comparisons or mathematical operations, if any, are described.

In claims 12-13 and 16-17, the recitation of "corresponding" is indefinite because it is not clear how correspondence is determined or what entities correspond. In addition, The recitations of "this [polarization] value", "those produced" and "standard solutions" lack antecedent bases.

#### ***Allowable Subject Matter***

Claims 9-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

As evidenced by the STIC Search Report submitted June 22, 2004 and a second STIC Search Report submitted herewith, the cited prior art does not appear to teach or suggest any of the methods of claims 9-19 involving the chelate-fluorophore tracer composition of claims 1 or 3.

#### ***Conclusion***

Claims 9-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci  
Examiner  
Art Unit 1641

djv



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SUPERVISORY PATENT EXAMINER  
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12/13/09